DEPARTMENT OF HEALTH AND HUMAN SERVICES

91537d

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

July 13, 2001

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 01-64

William Cherry, Director of Quality Assurance and Regulatory Compliance
Aventis Bio-Services
1020 First Avenue
P.O. Box 61501
King of Prussia, Pennsylvania 19406-0901

WARNING LETTER

Dear Mr. Cherry:

We inspected your firm, Aventis Bio-Services d.b.a. SeraMed BioCenter located at 351 Belmont Street NE, Salem, Oregon, from May 7-11, 2001. During that inspection our investigator documented violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act and Title 21, Code of Federal Regulations (21 CFR), Parts 600-680 as follows:

1. Failure to take adequate steps to prevent the contamination of the blood and plasma [21 CFR 640.64(e)], in that during the collection of plasma, for procedure # [redacted], the plasma bottle was not connected to the donor tubing. The plasma collected emptied into a trash can from the open effluent line creating an open line to the donor.

2. Failure to assure that each donor is certified to be in good health by the examining physician [21CFR 640.63(b)(3)]. Two donor's ("[redacted]", February 12, 2001 and "[redacted]" January 3, 2001) examinations were not completed in that the results of the HEENT, lymph nodes, chest, heart, abdomen, liver, spleen, neurological, and skin exams, were not documented on the Physical Examination Record as required.

3. Failure to maintain records concurrently with the performance of each significant step in the collection, processing, storage, and distribution of blood components [21 CFR 606.160(a)(1)] in that:

a. The records of the events for procedure # [redacted] were not made at the time of the event. The Quality Assurance Specialists (QAS) completed the "Exception Log" the following day, April 9, 2001.

b. On March 2, 2001, an overdraw occurred during the donation of unit # [redacted]. The log indicates an unspecified "Late entry." Quality Assurance review was completed on March 6, 2001, beyond the 48-hour limit required by your procedure. The log was completed by a technician other than the phlebotomist or disconnecting (dc'ing) technician involved in the incident. It also appears that all entries in the log are recorded as "dc'd donor." Although it is true that the donor was eventually disconnected, it wasn't until after the overbleed occurred.

c. An unspecified incident occurred on November 24, 2000, during the donation of unit # [redacted] The Exception log entry simply indicates a "problem phlebotomy," but does not identify the nature of the problem. The Donor file also fails to reflect what the problem was and refers to the exception log. The exception log shows an initial entry of an error code of "24" which is lined out and dated (not initialed) and "NA" was recorded in its place. There is no error code "NA" and no new code was recorded. In addition, the exception log was not filled out until November 29, 2000, five days following the incident and the person directly involved in the incident did not complete the record.

d. On at least three occasions, donation # 46809377 on March 9, 2001, donation # [redacted] on February 9, 2001, and donation # [redacted] on January 27, 2001, where "problem phlebotomies" or "clots/kinked lines" were recorded, the exception log was completed by someone not directly involved in the incident. For donation # [redacted] the exception log recording shows the date as January 22, 2001, five days before the donation.

We are also concerned that your SOP for Automated Machine Incidents (Exceptions) does not identify who is responsible for completing the entry of incidents and does not require or address concurrent documentation.

4. Failure to perform daily performance checks of the temperature recorder against a thermometer [21 CFR 606.60(b)], in that from April 14 to April 18, 2001, the temperature recording graph for freezer #2 stopped rotating. Three different employees documented that they performed the morning temperature checks, which entails comparing the recorder chart to a thermometer, during the period from April 14-18, 2001, yet none noted that the graph was not rotating until April 18, 2001, when the chart was changed and the mechanism restarted.

The recording of a step that did not actually take place is a serious deviation and could be considered a violation of Title 18 U.S.C., which is a criminal act.

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility as Authorized Official to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes license suspension and/or revocation, seizure, and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, 22201 23rd Drive SE, Bothell, Washington 98021-4421, Attention: Bruce W. Williamson, Compliance Officer.

Sincerely,

Charles M. Breen
District Director

cc: Mr. Ruedi E. Wager, President and CEO
Aventis Bio-Services
1020 First Avenue
P.O. Box 615 01
King of Prussia, Pennsylvania 19406-0901

cc: Ms. Kimberly M. Bachmeier, Center Manager
SeraMed BioCenter
351 Belmont Street NE
Salem, Oregon 97301